

Application Number: 10/679,271

Reply To Office Action Of NOVEMBER 24, 2004

**Amendments to the Claims**

1. (Currently Amended) A method for filling and sealing containers comprising at least one fluid receiving opening, at least one flexible component, a relaxed state interior volume, and non-relaxed state interior volume, wherein said non-relaxed state volume is greater than or equal to said relaxed state volume, and wherein said at least one flexible component has at least one external and at least one internal surface, said method comprising:
  - releasably retaining said container wherein said retention allows movement of said at least one flexible component;
  - positioning said retained container in a position to receive a fluid to be contained therein through said at least one fluid receiving opening;
  - expanding the relaxed state interior volume of said container to said non-relaxed state interior volume;
  - dispensing a fluid into said non-relaxed interior volume of said container;
  - subjecting both the exterior of said at least one flexible component and the interior volume of said fluid containing container and said fluid to an environment having a predetermined pressure range wherein said pressure range is greater than or equal to the vapor pressure of said fluid within said container;
  - sealing said at least one fluid receiving opening while said interior volume and said flexible component exterior are within said predetermined pressure range;
  - increasing the pressure of said environment to ambient atmospheric pressure; and
  - releasing said container from said releasably retained position.

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2. (Original) The method of claim 1 wherein the steps are performed under aseptic conditions.
3. (Original) The method of claim 1 wherein the steps are performed in the order recited.
4. (Original) The method of claim 1 wherein one or more steps are performed essentially simultaneously.
5. (Original) The method of claim 1 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by flexing said at least one flexible component.
6. (Original) The method of claim 1 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by injecting a gas into said container interior volume.
7. (Original) The method of claim 6 wherein said gas is an inert gas.
8. (Original) The method of claim 1 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by the application of vacuum or reduced pressure on said flexible component external surface.
9. (Original) The method of claim 1 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by physical manipulation of said flexible component.
10. (Currently Amended) The method of claim [10]9 wherein said physical manipulation is performed mechanically.

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11. (Original) The method of claim 1 wherein the dispensing and sealing steps are performed at separate physical locations.
12. (Original) The method of claim 1 further comprising inserting a fluid dispensing nozzle into said at least one fluid receiving opening prior to dispensing said fluid.
13. (Original) The method of claim 1 further comprising the manipulation of the fluid meniscus formed within said interior volume to increase or reduce the headspace to a predetermined range by a physical movement of said flexible component.
14. (Original) The method of claim 13 wherein the physical movement of said at least one flexible component is performed by expanding or contracting said at least one flexible component.
15. (Original) The method of claim 1 wherein said container further comprises a third interior volume when said container is filled with fluid and sealed.
16. (Original) The method of claim 15 wherein said non-relaxed state interior volume is greater than said filled and sealed volume of said container.
17. (Original) The method of claim 1 wherein said at least one component internal surface is hydrophilic.
18. (Original) The method of claim 1 wherein said at least one component internal surface is hydrophobic.
19. (Original) The method of claim 1 wherein said at least one component internal surface is wettable.

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20. (Original) The method of claim 1 wherein said container comprises more than one flexible component.
21. (Original) The method of claim 1 wherein said container at least one flexible component comprises less than two-thirds of the total structural components of said container.
22. (Original) The method of claim 1 wherein said container at least one flexible component comprises more than two-thirds of the total structural components of said container
23. (Original) The method of claim 1 wherein said at least one fluid receiving opening further comprises an inverted hollow conical structure positioned therein such that the narrowest portion of said hollow conical structure opens to the interior volume of said container.
24. (Currently Amended) The method of claim [1]23 wherein said hollow conical structure is non-releasably positioned within said fluid receiving opening.
25. (Currently Amended) The method of claim [1]23 wherein said hollow conical structure is releasably positioned within said fluid receiving opening prior to the dispensing of said fluid.
26. (Original) The method of claim 23 wherein said at least one fluid receiving opening and said hollow conical structure are contiguous.
27. (Withdrawn) A containment device for a pharmaceutical liquid comprising at least one fluid receiving opening; at least one flexible component; at least one rigid component; a relaxed state interior volume; and a non-relaxed state interior volume, wherein said non-relaxed state volume is greater than or equal to said relaxed state volume.

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28. (New) A method for filling and sealing containers comprising at least one fluid receiving opening, at least one flexible component, at least one rigid component, a relaxed state interior volume formed between said at least one flexible component and at least one rigid component, and non-relaxed state interior volume, wherein said non-relaxed state volume is greater than or equal to said relaxed state volume, and wherein said at least one flexible component has at least one external and at least one internal surface, said method comprising:

releasably retaining said at least one rigid component of said container wherein said retention allows movement of said at least one flexible component;

positioning said retained container in a position to receive a fluid to be contained therein through said at least one fluid receiving opening;

expanding the relaxed state interior volume of said container to said non-relaxed state interior volume;

dispensing a fluid into said non-relaxed interior volume of said container;

subjecting only the exterior of said at least one flexible component and said fluid to an environment having a predetermined pressure range wherein said pressure range is greater than or equal to the vapor pressure of said fluid within said container and said pressure range is less than ambient atmospheric pressure;

sealing said at least one fluid receiving opening while said interior volume is within the pre-selected pressure range and said flexible component exterior are within said predetermined pressure range and a meniscus of said fluid is within a desired range;

increasing the pressure of said environment to ambient atmospheric pressure; and

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releasing said container from said releasably retained position.

29. (New) The method of claim 28 wherein the steps are performed under aseptic conditions.
30. (New) The method of claim 28 wherein the steps are performed in the order recited.
31. (New) The method of claim 28 wherein one or more steps are performed essentially simultaneously.
32. (New) The method of claim 28 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by flexing said at least one flexible component.
33. (New) The method of claim 28 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by injecting a gas into said container interior volume.
34. (New) The method of claim 33 wherein said gas is an inert gas.
35. (New) The method of claim 28 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by the application of vacuum or reduced pressure on said flexible component external surface.
36. (New) The method of claim 28 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by physical manipulation of said flexible component.

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37. (New) The method of claim 36 wherein said physical manipulation is performed mechanically.
38. (New) The method of claim 28 further comprising the manipulation of the meniscus formed within said interior volume to increase or reduce a headspace to fall within a predetermined headspace range by a physical movement of said flexible component.
39. (New) A method for filling and sealing containers in a retaining device, the container having at least one fluid receiving opening and at least one flexible component, wherein the container defines a variable interior volume including a relaxed state interior volume and non-relaxed state interior volume, and wherein the non-relaxed state volume is greater than or equal to the relaxed state volume, and wherein the flexible component has at least one external surface and at least one internal surface, the method comprising:
- positioning the container with respect to the retaining device such that the container is in a position to receive, through the fluid receiving opening, a fluid to be contained therein;
  - releasably retaining at least a portion of the container in a fixed position with respect to the retaining device such that the flexible component is movable;
  - displacing the flexible component of the container such that the interior volume is expanded from the relaxed state interior volume to the non-relaxed state interior volume;
  - dispensing a fluid into the interior volume of the container;
  - subjecting each of the external surface of the flexible component, and the interior volume of the container, and the fluid disposed in interior volume to a single

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pressure, the single pressure being within a predetermined pressure range, wherein each pressure within the pressure range is greater than or equal to the vapor pressure of the fluid within the container and each pressure is less than ambient atmospheric pressure;

sealing the fluid receiving opening while the interior volume and the external surface of the flexible component are within the predetermined pressure range; and releasing the container from the releasably retained position.

40. (New) The method of claim 39 wherein the steps are performed under aseptic conditions.
41. (New) The method of claim 39 wherein the steps are performed in the order recited.
42. (New) The method of claim 39 wherein one or more steps are performed essentially simultaneously.
43. (New) The method of claim 39 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by flexing said at least one flexible component.
44. (New) The method of claim 39 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by injecting a gas into said container interior volume.
45. (New) The method of claim 44 wherein said gas is an inert gas.



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46. (New) The method of claim 39 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by the application of vacuum or reduced pressure on said flexible component external surface.
47. (New) The method of claim 39 wherein the expansion of the relaxed state interior volume of said container to said non-relaxed state interior volume is performed by physical manipulation of said flexible component.
48. (New) The method of claim 36 wherein said physical manipulation is performed mechanically.
49. (New) The method of claim 39 further comprising the manipulation of a meniscus of said fluid formed within said interior volume to increase or reduce a headspace to fall within a predetermined headspace range by a physical movement of said flexible component.